

CLAIMS

1. A process for preparing a dosage form, which affords a low viscosity solution when placed in the mouth of the consumer, which process comprises the steps of
 - (a) preparing a hydrated polymer composition comprising pullulan and sodium alginate having a viscosity suitable for casting;
 - (b) casting said composition into the shape of a dosage form; and
 - (c) drying said dosage form under such conditions as to provide a form which rapidly dissolves and disperses in the mouth of the consumer.
2. A process according to Claim 1, which process comprises the steps of
 - (a) preparing a hydrated polymer composition comprising pullulan, sodium alginate and one or more pharmaceutically active agents, which composition has a pH in the range 3.5 to 4.0, said pH being achieved by the addition of a suitable volatile acid;
 - (b) casting said composition into the shape of a dosage form; and
 - (c) drying said dosage form under such conditions as to volatilise the acid and provide a form which rapidly dissolves and disperses in the mouth of the consumer.
3. A process according to Claim 2, wherein the volatile acid is hydrochloric acid, acetic acid, or formic acid.
4. A process according to Claim 1, which process comprises the steps of
 - (a) preparing a hydrated polymer composition comprising pullulan, sodium alginate and one or more pharmaceutically active agents,

which composition has a pH in the range 3.5 to 4.0, said pH being achieved by the addition of a suitable non-volatile acid;

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- (b) casting said composition into the shape of a dosage form; and
- (c) drying said dosage form to provide a form which rapidly dissolves and disperses in the mouth of the consumer when exposed to the buffering effect of saliva.

10 5. A process according to Claim 4, wherein the non-volatile acid is aspartame, aspartic acid, benzoic acid, citric acid, gluconic acid, glutamic acid, malic acid, phosphoric acid, saccharin, sorbic acid, succinic acid, or tartaric acid.

15 6. A process according to Claim 4 or 5, wherein the dosage form is buffered in the mouth to a pH of 4.0 or greater.

7. A process according to any of Claims 2 to 6, wherein the pH of the composition is adjusted in step (a) to a pH of 3.5.

20 8. A process according to Claim 1, which process comprises the steps of

25 (a) preparing a hydrated polymer composition comprising pullulan, sodium alginate and one or more pharmaceutically active agents, which composition additionally comprises one or both of the enzymes pullulanase and alginate lyase;

(b) casting said composition while still viscous into the shape of a dosage form; and

30 (c) drying said dosage form to provide a form which rapidly dissolves and disperses in the mouth of the consumer.

9. A process according to Claim 1, which process comprises the steps of

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- (a) preparing a hydrated polymer composition comprising pullulan, sodium alginate and one or more pharmaceutically active agents;
 - (b) casting said composition into the shape of a dosage form;
 - (c) drying said dosage form; and
 - (d) irradiating said dosage form with gamma-radiation to provide a form which rapidly dissolves and disperses in the mouth of the consumer.
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10. A process according to Claim 9, wherein said gamma-irradiation is in an amount of 25 kGy or 40 kGy.
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11. A process according to any of Claims 1 to 10, wherein the solution formed upon dissolution of the resulting dosage form in the mouth of the consumer has a viscosity, which is less than 80% that of the composition formed in step (a).
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12. A process according to any of Claims 1 to 11, wherein step (c) is carried out in a fan oven at a temperature of from 50°C to 80°C for a period of from 15 to 90 minutes.
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13. A process according to any of Claims 1 to 11, wherein step (c) is carried out in a coating machine at a temperature of from 20°C to 150°C.
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14. A dosage form obtainable according to a process described in any of Claims 1 to 13.
15. A dosage form according to Claim 14, wherein pullulan is present in an amount of from 5 to 45 wt%.
16. A dosage form according to Claim 15, wherein pullulan is present in an amount of from 15 to 25 wt%.

17. A dosage form according to Claim 16, wherein pullulan is present in an amount of 20 wt%.
- 5 18. A dosage form according to Claim 14, wherein sodium alginate is present in an amount of from 0.1 to 2.5 wt%.
19. A dosage form according to Claim 18, wherein sodium alginate is present in an amount of 0.5 wt%.
- 10 20. A dosage form according to any of Claims 14 to 19, wherein the pharmaceutically active agent is
 - an anti-cholesterolaemic;
 - an anti-diarrhoeal;
 - 15 an anti-emetic;
 - an anti-fungal;
 - an anti-histamine;
 - an anti-infective (including anti-microbial agents);
 - an anti-inflammatory;
 - 20 an anti-parasitic agent;
 - an anti-Parkinsonism drug;
 - an anti-pyretic (including analgesic anti-pyretics);
 - an anti-tussive/cough suppressant;
 - a bronchodilator;
 - 25 an appetite stimulant;
 - a cardiovascular drug (including anti-hypertensives);
 - a decongestant;
 - a drug for treating gastric disorders;
 - a drug for renal failure;
 - 30 a drug which selectively modifies CNS function;
 - an expectorant;
 - a general non-selective CNS depressant;
 - a general non-selective CNS stimulant;
 - an H₂-antagonist;

- a narcotic analgesic;
a non-steroidal anti-inflammatory drug;
oral insulin;
a PDE5 inhibitor;
5 a proton pump inhibitor;
a psychopharmacological drug; or
a wound-healing drug.
21. A dosage form according to Claim 20, wherein the pharmaceutically active
10 agent is ibuprofen, ivermectin, or any form of eletriptan.
22. A dosage form according to Claim 21, wherein the pharmaceutically active
agent is eletriptan hydrobromide (RelpaxTM) or eletriptan hemisulphate.
- 15 23. A dosage form according to any of Claims 14 to 22, wherein the
pharmaceutically active agent is present at a concentration of from 0.1 to 75%
w/w.
24. A dosage form according to any of Claims 14 to 23, wherein the
20 pharmaceutically active agent is an oral healthcare product.
25. A dosage form according to Claim 24, wherein the oral healthcare product is
one or more of a deodorising agent, an anti-microbial agent, or a salivary
stimulant.
- 25 26. A dosage form according to Claim 24 or 25, wherein the oral healthcare
product is present at a concentration of from 0.1 to 15% w/w.
27. A dosage form according to any of Claims 14 to 26, which dosage form is in
30 the form of a film.
28. A dosage form according to any of Claims 14 to 27, which dosage form is
orally consumable.

29. A dosage form according to any of Claims 14 to 28, which dosage form is suitable for human or veterinary use.